

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/438,600 11/12/99 SHIEH

C 99.723

020306 HM22/0104
MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO IL 60606

EXAMINER

PHAM, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

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DATE MAILED:

01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/438,600 | SHIEH ET AL. | |
| | Examiner | Art Unit | |
| | Minh-Quan K. Pham | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 November 2000.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 and 21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____ .
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 20) Other: _____

DETAILED ACTION

The amendment filed November 15, 2000, has been entered as Paper No. 8.

Claim Status

Claims 1-15 and 21 are pending. Claims 16-20 are cancelled in Paper No. 8. Claim 21 is added in Paper No. 8.

Claim Rejections - 35 USC § 112

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn in light of amendment presented in Paper No. 8.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 8-9, 12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866). The rejection is maintained.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, 12, and 14-15 above, and further in view of Hancock et al. (US 5,716,825). The rejection is maintained.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, 12, and 14-15 above, and further in view of Lofas et al. (1990), *Chemical Communications*, pp. 1526-1528. The rejection is maintained.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, and 12 above, and further in view of Zanzucchi et al. (US 5,585,069). The rejection is maintained.

NEW REJECTION

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, 12, and 14-15 above, and further in view of Lofas et al. (1990), *Chemical Communications*, pp. 1526-1528.

See previous office action for the disclosure of Machida et al. in view of Lofas et al.

Response to Arguments

Applicants argue that Machida et al. do not teach the use of multiple sample treating zones. Although Machida et al. do not explicitly disclose multiple sample treating zones, the teaching of Machida et al. renders the instant invention obvious, because the instant invention is merely a duplication of parts of the device of Machida et al., and thus, has no patentable significance (see MPEP 2144.04).

In response to applicants' argument that the instant device provide "an effective solution to maximize hybridization efficiency" of DNA, the examiner must points out that claim 1, the only independent claim, do not mention DNA hybridization. Only claims 8-9 have DNA as the specific binding pair member. Claims 8-9 are rejected over Machida et al. in view of Hancock et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references (Machida et al. and Hancock et al) are suggested by Hancock et al. In column 6, lines 7-15, Hancock et al. clearly teach that alternative binding partners can be antibodies, which suggest that the microfluidic device can be used for immunoassay as well as DNA hybridization.

In response to applicants' argument that Lofas et al. only teach the use of hydrogels for adherence of probes to metal surfaces, applicants are reminded that the instant claims do not

exclude metal surfaces. Further, entrapment of biological molecules in hydrogels are well known in the art and would have been within the knowledge of one of ordinary skill in the art (see also Chang (1975), In *Immobilized Enzymes, Antigens, Antibodies, and Peptides* (Eds. Weetall), New York: Marcel Dekker, Inc, p. 245-292, especially page 253, second full paragraph). Moreover, hydrogels are porous material which would have been obvious to use in the device of Machida et al., because of its high immobilization capacity.

In summary, applicants' arguments filed November 15, 2000, have been fully considered but they are not persuasive for the reasons discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

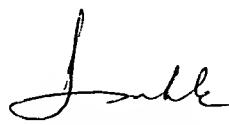
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham, Ph.D., whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.
December 29, 2000


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
01/02/01